Attorney Docket No. 0702-044861

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

All pending claims are cancelled.

Please add new claims 28-55 as follows:

- 28. (New) Excipient for dry powder inhalation preparations comprising granules made of primary carrier material, which granules break down during inhalation in such a manner that they give a concentration of primary carrier material at stage 2 of the twin stage impinger of at least 5%, which excipient is obtainable by granulating a primary carrier material in a fluid binding agent and drying the granules thus obtained.
- 29. (New) Excipient as claimed in claim 28, wherein the concentration of primary carrier material at stage 2 of the twin stage impinger is at least 10%.
- 30. (New) Excipient as claimed in claim 28, wherein the concentration of primary carrier material at stage 2 of the twin stage impinger is at least 20%.
- 31. (New) Excipient as claimed in claim 28, wherein the fluid binding agent is an aqueous solution of the primary carrier material.
- 32. (New) Excipient as claimed in claim 28, wherein the fluid binding agent is a solvent, in particular ethanol.
- 33. (New) Excipient as claimed in claim 28, wherein the fluid binding agent is water.
- 34. (New) Excipient as claimed in claim 28, wherein the drying is performed in an oven.

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35. (New) Excipient as claimed in claim 28, wherein the drying is performed while the granules are kept in motion, such as in a fluid bed dryer.

36. (New) Excipient according to claim 28, wherein the particle size of the granules lies between $50 - 1000 \mu m$.

37. (New) Excipient according to claim 28, wherein the particle size of the granules lies between 200-500µm.

38. (New) Excipient according to claim 28, wherein the primary particle median geometric size of the granules lies in the range $1-170\mu m$.

39. (New) Excipient according to claim 28, wherein the primary particle size median geometric size of the granules lies in the range 1-15μm.

- 40. (New) Excipient according to claim 28, wherein the primary carrier material is a monosaccharide, such as glucose, fructose, mannose; a polyol derived from these monosaccharides, such a sorbitol, mannitol or their monohydrates; a disaccharide, such as lactose, maltose, sucrose, polyol derived from these disaccharides, such as lactitol, mannitol, or their monohydrates; an oligo or polysaccharide, such as dextrins and starches.
- 41. (New) Excipient according to claim 28, wherein the primary carrier material is a crystalline sugar such as glucose, lactose, fructose, mannitol or sucrose.
- 42. (New) Excipient according to claim 28, wherein the primary carrier material of the granules is lactose.
- 43. (New) A dry powder inhalation formulation which contains a pharmacologically active component and an excipient according to claim 28, for delivery of the active component to the lungs.

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- 44. A dry powder inhalation formulation according to claim 43, in which the active component is selected from the group consisting of sterioids, bronchodilators, cromoglycate, proteins, peptides and mucolytics.
- 45. (New) A dry powder inhalation formulation according to claim 43, in which the active component is selected from the group consisting of hypnotics, sedatives, analgesics, anti-inflammatory agents, anti-histamines, anti-convulsants, muscle relaxants, anti-spasmodics, anti-bacterials, anti-biotics, cardiovascular agents and hypoglycaemic agents.
- 46. (New) Method for producing an excipient as claimed in claim 28, comprising granulating a primary carrier material in a fluid binding agent and drying the granules thus obtained.
- 47. (New) Method as claimed in claim 46, wherein the fluid binding agent is an aqueous solution of the primary carrier material.
- 48. (New) Method as claimed in claim 46, wherein the fluid binding agent is a solvent, in particular ethanol.
- 49. (New) Method as claimed in claim 46, wherein the fluid binding agent is water.
- 50. (New) Method as claimed in claim 46, wherein the drying is performed in an oven.
- 51. (New) Method as claimed in claim 28, wherein the drying is performed while the granules are kept in motion, such as in a fluid bed dryer.

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52. (New) Lactose granules for use in dry powder inhalation preparations,

wherein the granules break down during inhalations in such a manner that they give a

concentration of primary carrier material at stage 2 of the twin stage inpinger of at least 5%.

53. (New) Lactose granules according to claim 52, wherein the granules

break down during inhalation in a manner that they give a concentration of primary carrier

material at stage 2 of the twin stage impinger of at least 10%.

54. (New) Lactose granules according to claim 52, wherein the granules

break down during inhalation in a manner that they give a concentration of primary carrier

material at stage 2 of the twin stage inpinger of at least 20%.

55. (New) Use of an excipient as claimed in claim 46 for the preparation

of a dry powder inhalation preparation for the treatment of diseases of the respiratory tract.